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September 29, 2008

Michael A. Carome, M.D., Captain
U.S. Public Health Service
Office for Human Research Protections
Rockville, MD
Sent to: humansubjectstraining@hhs.gov

Re: Request for Information and Comments on the Implementation of Human Subjects
Protection Training and Education Programs

Dear Dr. Carome:

On behalf of the American Association for the Advancement of Science (AAAS) and its Committee on Scientific Freedom and Responsibility (CSFR), we are pleased to have the opportunity to comment on the Office for Human Research Protections' Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs (<http://www.hhs.gov/ohrp/requests/>). It is critically important that institutions provide training on human subjects research and that OHRP have a role in ensuring that institutions offer such training to all those involved in conducting and administering human subjects research.

While we can cite anecdotal evidence of situations where we believe that additional education could have prevented non-compliance with existing rules and policies, and perhaps avoided harm to subjects, there is a lack of evidence-based studies documenting where and how further training could be most effectively implemented. Having such documentation in hand would make the value and need for a rigorous education program more obvious to the research community. In the absence of such evidence, it would be premature to issue a regulation. Even a guidance document would benefit from more rigorous assessment of how training and educational programs could be effectively implemented. Toward that end, we strongly urge OHRP to take a leadership role in encouraging and supporting studies on the effectiveness of training in increasing compliance with existing requirements and in promoting a research culture that gives priority to the protection of human subjects while also valuing the different perspectives and methods used by researchers from diverse fields.

In considering what type of guidance would be most helpful to the research community, OHRP should encourage and promote a number of approaches for human subjects protection training. For example, medical scientists have much different needs, approaches, and ethical issues to consider than do social scientists when pursuing human subjects research. Even within the medical field, working with human tissue is vastly

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different from working directly with patients. Furthermore, given their distinctive roles in the conduct of research, a principal investigator will likely benefit from a different educational program than an institutional review board (IRB) member. Any guidance issued by OHRP must take these various needs into consideration.

To maintain consistent and high-quality training programs at institutions, we urge that OHRP issue clear guidance on the following:

- The **objectives** of a human subjects protection training program.
- Those who should **develop, provide** and **receive** training.
- The **issues** that should be a part of training, with clear recognition of the importance of designing curricula that take into account differences among the research methods and needs of different disciplines.
- The provisions for **continuing education**.
- The need to **evaluate** the training's effectiveness and recommendations for doing so.

AAAS is the world's largest multi-disciplinary science society, representing the interests of ten million scientists worldwide, and publisher of the prestigious peer-reviewed journal *Science*.

Sincerely,



Alan I. Leshner
Chief Executive Officer



Joseph G. Perpich
Chair, AAAS Committee on
Scientific Freedom and Responsibility